

REMARKS

Status of the claims

Claims 1, 2, 4-6, 8, 13-26, 28-32, 34-37, 43, 44, 50, 51, 61 and 62 are pending in the application. Claims 1, 8 and 31 are currently amended. Claims 3, 7, 9-12, 27, 33, 38-42, 45-49, 52-60 are previously canceled. Claim 30 is canceled herein. Claims 1, 2, 4-6, 8, 13-26, 28-32, 34-37, 43, 44, 50, 51, 61 and 62 are rejected. No new matter is added.

Claim amendments

Claims 1, 8 and 31 are amended and claim 30 is canceled to overcome rejections under 35 U.S.C. § 112, 35 U.S.C. § 102 and 35 U.S.C. § 103 as discussed below. Claim 1 is amended to incorporate the limitations of dependent claim 30 in lieu of which claim 30 is herein canceled. Claim 1 now additionally recites a means to collect a tissue or biochemical sample during tissue ablation such that this means is operably connected to the device of the instant invention. Claim 31 is amended to depend from amended claim 1. Claim 8 is amended to delete the terms rheologic materials, shape memory materials and explosive discharge. No new matter is added.

Objection to the drawings

The drawings are objected to under 37 CFR 1.83(a). The Examiner states that the container operably connected to the device for supplying the abrasive as recited in claim 1 or connected to collect biomolecules as recited in

claim 30 are not shown in the drawings. Applicants have amended figure 4 to incorporate both these containers and submit herewith the amended figure in a sheet marked as replacement sheet. No new matter is added as the means to contain the abrasive and the means to collect the biomolecule are described in the specification (for example on page 25, lines 5-16). Accordingly Applicants respectfully request that the objection to the drawings be withdrawn.

Claim rejection under 35 U.S.C. § 112, first paragraph

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Applicants respectfully traverse this rejection.

The Examiner states that the specification is not enabling in how a pressurized gas, explosive discharge, rheologic materials, or shape-memory materials function as a means to drive an abrasive member at high frequencies. Applicants have amended claim 8 to delete the terms rheologic materials, shape memory materials and explosive discharge. Applicants submit that **Weaver** (US Pub. No. 2002/006553 A1) gives an example of the use of a pressurized gas to accelerate microparticles to ablate tissue. In a similar fashion pressurized gas may be used to cause movement of the abrasive member of the instant device. In view of this example Applicants have retained pressurized gas as a means to drive the abrasive member at high frequencies. Accordingly amended claim 8 is adequately enabled by the instant specification and what is known in the related art. In view of

the amendments and arguments presented above, Applicants respectfully request that the rejection of claim 8 under 35 U.S.C. 112, first paragraph, be withdrawn.

Claim rejections under 35 U.S.C. § 102

Claims 1, 2, 3, 4, 5, 6, 8, 14, 18, 19, 21-26 and 62 are rejected under 35 U.S.C. § 102(b) as being anticipated by **Suroff** (US patent No. 5, 150,492). Applicants respectfully traverse this rejection.

The Examiner states that **Suroff** discloses a device for altering tissue comprising an abrasive member contacting abrasive material on tissue or thereon and means to drive the member at high frequency. The device is capable of use with various tissues and various lubricants, i.e. water, and pharmaceuticals. Applicants respectfully disagree.

Suroff teaches an ultrasonic toothbrush with an exchangeable ultrasonic implement, which can be connected to an ultrasonic power means. The ultrasonic toothbrush is designed to remove tartar, stain as well as interproximal deposits for efficient cleaning of teeth (col. 7, ll. 19-24). This ultrasonic toothbrush is specifically designed such that adults and children (col. 2, ll. 66-67) can safely use it at home without special knowledge or training.

The Examiner states on page 8, (response to arguments section) that the device disclosed by **Suroff** is capable of ablating tissue, even if the particular method of ablating tissue is not described. If this were true then **Suroff's** device would ablate and harm gums when used either by adults or children. In **Suroff's** invention, the use of relatively soft bristle materials in

combination with low energy ultrasonic vibrations (col. 9 ll. 44-52) renders the use of the device on a regular basis with no deleterious affect on the surface that the bristles come in contact with during the cleaning process.

The Examiner further states that **Suroff's** device displays cavities that can contain a pharmaceutical compound and a structure that can support dispensing such pharmaceutical compounds (pg. 8, response to arguments section). Applicants respectfully disagree. The figures in **Suroff's** application does not display any cavities that can be used to contain a pharmaceutical compound nor is there any reference to such cavities in the specification. Furthermore the invention does not allude to a structure that is capable of dispensing any compound contained in any such cavity. Furthermore, **Suroff** does not disclose a means of collecting a tissue or biological sample, which is operably connected to the device.

Applicants' device has a separate container, which can store a pharmaceutical compound and this container is operably connected to the device. This device further has a means operably connected to the device for collecting a tissue or biochemical sample during tissue ablation. Accordingly, Applicants submit that **Suroff** does not teach every element as set forth in claim 1 and neither are the claim elements inherent to **Suroff's** device as explained supra. Thus, claim 1 is not anticipated by **Suroff** and as claims 2, 3, 4, 5, 6, 8, 14, 18, 19, 21-26 and 62 depend directly or indirectly from amended independent claim 1, they are novel and not anticipated by **Suroff**. Accordingly, Applicants

respectfully request that the rejection of claims 1, 2, 3, 4, 5, 6, 8, 14, 18, 19, 21-26 and 62 under 35 U.S.C. § 102(b) be withdrawn.

Claims 1, 2, 4-6, 8, 13-18, 20-26 and 62 are rejected under 35 U.S.C. § 102(a) as being anticipated by **Bernaz** (WO 02/053046, US pub. No. 2004/0092956, English version). Applicants respectfully traverse this rejection.

The examiner states that **Bernaz** discloses a device for altering or ablating tissue comprising an abrasive member contacting abrasive material on tissue or thereon, electro or magneto responsive material (motor) means to drive the abrasive member at high frequency, abrasive material of aluminum oxide 50-90 microns, lubricant comprising water and electrophoretic driving means, and a container formed by ridges capable of holding pharmaceuticals until delivery by mechanical pressure (PPs 0019, 0025, 0031-0032, 0046-0047, 0052, 0055, and 0062-0063). The Examiner further states (pg. 8, responseto arguments section) that **Bernaz's** device has cavities that can be used to contain pharmaceuticals and that the device has a structure capable of deliver such pharmaceuticals applying mechanical pressure. Applicants respectfully disagree.

Bernaz teaches a skin dermabrasion device by gently contacting the skin with an abrasive and comprises a curved abrasive surface held by a support mounted in a housing, which is driven to oscillate about its axis. Applicants are not able to locate in any of the figures or in the specification any reference to cavities that can hold pharmaceutical compounds. Furthermore there is no reference in the figures or in the specification about a structure that

can cause delivery of the pharmaceutical compound contained in a cavity by application of mechanical pressure. These properties attributed to the device by the Examiner are neither expressly nor inherently described in **Bernaz's** invention.

Bernaz teaches that microepidermabrasion using the apparatus of the invention may be followed by application of a treating product that is made to penetrate the skin tissue by application of a high energy electromagnetic flux of energy and or by applying electromagnetic radiation (0032). However **Bernaz** does not teach that the treating product is contained in a separate container operably attached to the device or that the means to deliver such a treating product is present on the device. Furthermore, **Bernaz** does not teach a means operably connected to the device for collection of a tissue or biological sample as recited in currently amended claim 1. Thus **Bernaz** cannot anticipate claim 1 as all the elements of amended claim 1 are not taught by **Bernaz**. Claims 2, 4-6, 8, 13-18, 20-26 and 62 depend either directly or indirectly from amended claim 1 and hence are also novel and not anticipated by **Bernaz**. Accordingly Applicants respectfully request that the rejection of claims 1, 2, 4-6, 8, 13-18, 20-26 and 62 under 35 U.S.C. § 102(a) be withdrawn.

Claims 1, 2, 4-6, 8, 13-26, 28, 30, 31, 34-37, 43, 44 and 62 are rejected under 35 U.S.C. § 102(e) as being anticipated by **Weaver** (US Pub. No. 2002/006553 A1). Applicants respectfully traverse this rejection.

The Examiner states that **Weaver** discloses a device for ablating tissue using an abrasive member that can be driven at high frequencies to contact abrasive material delivered onto a tissue via a container (0042-0045). The Examiner further states that the pressurized gas driving forces disclosed by **Weaver** are capable of driving microparticles at high frequencies and that the device has a means to contain pharmaceuticals which can be delivered by electrophoresis. The examiner states that **Weaver** discloses collecting biomolecules for sampling (0014), and electrodes, conductive fluid interface, and controller capable of monitoring electrical property of the tissue (0017, 0018). Applicants respectfully disagree.

Weaver discloses an apparatus used for creating microconduits by impingement of accelerated microparticles thereon for localized molecular and ionic transport to/from tissue (Abstract). The device comprises a means for accelerating a plurality of microparticles to a velocity that causes penetration into a tissue surface upon impingement thereon, a means for directing the microparticles towards a region of tissue surface and a means to allow the microparticles to impinge and to penetrate a region of the tissue surface (0065). The means to direct the microparticle is a mask such as a membrane comprising one or more microholes through which the microparticle may penetrate the tissue surface (0068). Or is a beam collimator to direct a scannable collimated beam of microparticles toward the tissue surface (0076). The means to allow the microparticles to impinge and penetrate the tissue may be a gating switch or other ON/OFF means or a timing or metering device (0079-0081).

As recited in amended claim 1, the instant device comprises an abrasive member either contacting the abrasive material disposed on the tissue surface or having the abrasive material attached thereon and a means to drive the member at a high frequency against the abrasive/or the tissue surface. **Weaver** does not teach a device having such an abrasive member. The abrasive material in **Weavers** invention is not disposed on the tissue surface nor contained in a separate container operably connected to the device, but rather are suspended in a fluid or as loose particulates until a force accelerates the abrasive/microparticels from the device toward the tissue surface.

At minimum, absent teachings of the abrasive member disclosed in Applicants amended claim 1, **Weaver** cannot anticipate amended claim 1 as all the claim elements are not taught by **Weaver**. Claims 2, 4-6, 8, 13-26, 28, 30, 31, 34-37, 43, 44 and 62 depend either directly or indirectly from amended claim 1, they are also not anticipated by **Weaver**. Accordingly Applicants respectfully request that the rejection of claims 1, 2, 4-6, 8, 13-26, 28, 30, 31, 34-37, 43, 44 and 62 under 35 U.S.C. § 102(e) be withdrawn.

Claims 1, 2, 4-6, 8, 13, 14, 17, and 20-25 are rejected under 35 U.S.C. 102(e) as being anticipated by **Hickok** et al. (US Pub. No. 2003/0096213). Applicants respectfully traverse this rejection.

The Examiner states that **Hickok** discloses a device for ablating tissue using a diamond abrasive on the ablating device and a supply of

pharmaceuticals to be delivered to the ablation site. Applicants respectfully disagree.

Hickok et al. teaches a dental tool for use with an ultrasonic transducer. The tool has a shaft with a transducer at the proximal end and a tip at the distal end for performing dental procedures and furthermore the tool has a fluid passage extending from the proximal end to the distal end and exiting at a port at or near the tip (Abstract). In **Hickok's** invention a fluid passage in the device shaft holds a liquid pharmaceutical. **Hickok** does not teach a separate container operably connected to the device to hold a pharmaceutical compound. Nor does **Hickok's** device have a means for collecting tissue or biochemical sample such that this means is operably connected to the tool. Thus **Hickok** does not teach at least two elements that are novel to the instant device. As **Hickok** does not teach all the claim elements of amended claim 1, **Hickok** cannot anticipate claim 1. Furthermore as claims 2, 4-6, 8, 13, 14, 17, and 20-25 depend either directly or indirectly from independent amended claim 1, they are also not anticipated by **Hickok**. Accordingly, Applicants respectfully request that the rejection of claims 1, 2, 4-6, 8, 13, 14, 17, and 20-25 under 35 U.S.C. 102(e) be withdrawn.

Claim rejections under 35 U.S.C. § 103

Claims 34, 35, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Bernaz** as applied to claims 26 and 1 above, and further

in view of **Eggers** (US patent No. 6,066,134). Applicants respectfully traverse this rejection.

The Examiner states that **Bernaz** discloses the claimed invention except for monitoring feedback using an electrical property of the tissue with the device. The Examiner also states that **Eggers** teaches monitoring feedback using a heartbeat to perform a safe ablation procedure. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of **Eggers** in the device of **Bernaz** to increase the safety of the ablation procedure for better patient outcome. Applicants respectfully disagree.

Bernaz does not teach or suggest important elements of the instant device as discussed *supra*. **Eggers** et al. teach an electrosurgical probe comprising a shaft having an electrode array, as an active electrode, at its distal end, a return electrode recessed within the shaft having an electrode array, as active electrode, at its distal end, a return electrode recessed within the shaft and a connector at its proximal end for coupling the electrode array to a high frequency power supply (Abstract). **Eggers** et al teach monitoring the temperature of the surface of the electrode array to regulate current flow if the temperature exceeds selected limits (col. 14, ll. 44-63). **Eggers** et al. teach monitoring the heartbeat so that the high frequency voltage is pulsed to cut or ablate heart tissue to form a revascularization channel during systole of the heart and a thermal property of the tissue to perform safe ablation of heart tissue during a revascularization procedure (col. 23, ll. 43-56).

Applicants' invention as recited in amended claim 1 is discussed *supra*. **Bernaz** at minimum does not teach two important elements of amended claim 1. **Bernaz** does not teach or suggest the presence of a separate container to hold a pharmaceutical such that this container is operably connected to the microepidermabrasion device nor does **Bernaz** teach a means or structure for delivering the pharmaceutical at the site of tissue ablation. Furthermore **Bernaz** does not teach a means that is operably connected to the microepidermabrasion device for collection of a tissue or biochemical sample. Combining **Eggers et al** with **Bernaz** does not teach these novel elements of amended claim 1. Thus, amended claim 1 is non obvious over **Bernaz** in view of **Eggers**.

The effleuraging action of the abrasive surface of the device in **Bernaz** is continuous, gentle (pg. 1, paragraph 001) and does not require the application of high frequency voltage. Thus, one skilled in the art would find no motivation to even combine **Eggers et al.** with **Bernaz**. As amended claim 1 is not rendered obvious by the combination of **Bernaz** with **Eggers et al**, then neither are the claims 34, 35, 36 and 37, which depend on independent claim 1, rendered obvious by the combination. Accordingly, Applicants respectfully request that the rejection of claims 34, 35, 36 and 37 under 35 U.S.C. § 103(a) be withdrawn.

Claims 50 and 51 are rejected under 35 U.S.C. § 103(a) as being unpatentable over **Weaver** as applied to claim 1 above and further in view of **Eggers** (US patent No. 6,159,194). Applicants respectfully traverse this rejection.

The Examiner states that **Weaver** discloses the claimed invention including monitoring temperature, but is silent on the structure relied upon to monitor temperature (0117). The Examiner further states that **Eggers** teaches monitoring a thermal property of the tissue using infrared sensors and the use of an infra red detector and controller to analyze data from an energy source and detector is inherent in the disclosed device because it measures temperature. It would have been obvious to one of ordinary skill in the art to use the teachings of **Eggers** in the device of **Weaver** in order to maintain safe operating temperatures during the ablation procedure. Applicants respectfully disagree.

Weaver and **Eggers** are as described *supra*. **Weaver** does not teach a device having an abrasive member as disclosed in the Applicants device. **Weaver** teaches the impingement of microparticles to form conduits on a tissue surface for transport in/out of the tissue. The microparticles themselves are accelerated to form conduits on the tissue surface. There is no abrasive member to move these particles on the tissue surface. Combining **Eggers** et al with **Weaver** does not remedy this deficiency. Therefore amended claim 1 is non-obvious over **Weaver** et al in view of **Eggers** et al. As claims 50 and 51 depend indirectly from claim 1, the combination of **Eggers** et al and **Weaver** does not render them obvious. Accordingly, Applicants respectfully request that the rejection of claims 50 and 51 under 35 U.S.C. § 103(a) be withdrawn.

Claim 29 is rejected under 35 U.S.C. § 103(a) as being unpatentable over **Bernaz**, **Weaver** or **Hickok** as applied to claim 20 above, and

further in view of **Unger** (US patent No. 6,416,740). Applicants respectfully traverse this rejection.

The Examiner states that **Bernaz, Weaver** or **Hickok** discloses the claimed invention except for a reservoir with a permeable membrane to release a pharmaceutical to the tissue. **Unger** teaches the use of a permeable membrane to release a pharmaceutical in a patch applied to the skin of a patient. The examiner states that it would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of **Unger** in the device of **Bernaz, Weaver** or **Hickok** in order to provide a convenient drug delivery system through the skin to achieve therapeutic results. Applicants respectfully disagree.

Bernaz, Weaver and **Hickok** are as described *supra*. **Unger** teaches an acoustically active targeted therapeutic delivery system where ultrasound enhances delivery of the therapeutic (Abstract). The therapeutic, e.g. steroid prodrugs, together with a penetration enhancer may be administered transdermally in a patch or reservoir with a permeable membrane in a patch applied to the skin of a patient (col. 69, ll. 11-14).

Unger does not teach a device for ablating tissue. **Unger** rather teaches acoustically active micro spheres. **Unger** does not discuss attaching these microspheres or a reservoir filled with such micro spheres and sealed by a semipermeable membrane to a device. Nor does **Bernaz** teach or suggest that a reservoir containing a pharmaceutical maybe operably connected to the microepidermabrasion device, which is mainly suited for cosmetic skin treatment. So one skilled in the art would not be motivated to place a reservoir filled with

Unger's microspheres and sealed by a semipermeable membrane in **Bernaz's** microdermabrasion device. Thus the combination of **Bernaz** and **Unger** does not render amended claim 1, and by extension dependent claim 29, obvious.

Weaver does not teach a device having an abrasive member as disclosed in the Applicants device. **Unger** does not remedy this deficiency and thus the combination of **Weaver** and **Unger** does not render amended claim 1, and by extension dependent claim 29, obvious. In **Hickok's** invention a fluid passage in the device shaft holds a liquid pharmaceutical. **Hickok** does not teach a separate container operably connected to the device to hold a pharmaceutical compound. The liquid pharmaceutical is dispensed at the desired site via a port at the tip of the shaft. Thus one skilled in the art is not motivated to operably connect a reservoir filled with **Unger's** microspheres and sealed by a semipermeable membrane to **Hickok's** dental tool as this in no way improves **Hickok's** dental tool. Thus the combination of **Hickok** and **Unger** does not render amended claim 1, and by extension dependent claim 29, obvious. In view of the arguments presented above, Applicants respectfully request that the rejection of claim 29 under 35 U.S.C. § 103(a) be withdrawn.

Claims 19, 61 and 62 are rejected under 35 U.S.C. § 103(a) as being unpatentable over **Bernaz**, **Weaver** or **Hickok** as applied to claim 1 above and further in view of **Melbouci et al.** (US Patent No. 6, 562, 090). Applicants respectfully traverse this rejection.

The Examiner states that **Bernaz, Weaver et al.** or **Hickok** discloses the claimed invention except for using a lubricant of water and glycerol with the abrasive. The Examiner also states that **Melbouci et al.** teach using water and glycerol with a lubricant to provide a stabilized suspension of abrasive in lubricant (claim 1). Thus, the Examiner states that it would have been obvious to one of ordinary skill in the art at the time of the invention to use teachings of **Melbouci et al.** in the device of **Weaver et al.** in order to facilitate the use of the abrasive.

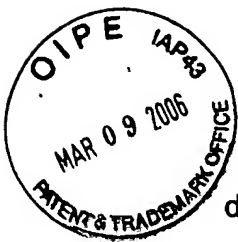
Bernaz, Weaver et al. and **Hickok** are as stated by the Applicants' *supra*. **Melbouci et al.** disclose a fluid abrasive for dentifrice systems, i.e., toothpastes, that may comprise the abrasive, a water-swellaable or water-soluble polymer and water mixed with glycerol (col. 3, ll. 10-44). As described *supra* each of **Bernaz, Weaver** and **Hickok** do not teach all the elements disclosed in Applicants' claim 1. **Melbouci et al.** does not remedy the deficiency in the teachings of **Bernaz, Weaver** or **Hickok**. Thus claim 1 is non obvious over **Bernaz, Weaver** or **Hickok** in view of **Melbouci et al.** As claim 19 is dependent from non-obvious amended claim 1, claim 19 is non-obvious. Furthermore, as claims 61 and 62 depend from non-obvious dependent claim 19, they are in turn non-obvious. Accordingly, Applicants respectfully request that the rejection of claims under 35 U.S.C. § 103(a) be withdrawn.

Claim 32 is rejected under 35 U.S.C. § 103(a) as being unpatentable over **Weaver** as applied to claim 31 above, and further in view of **Fuisz** (US Patent No. 3,918,433). Applicants respectfully traverse the rejection.

The Examiner states that **Weaver** discloses the claimed invention except for using cotton with the collection container. The Examiner further states that **Fuisz** teaches using cotton in a collection container to provide sorption capacity in excess of the container volume and it would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of **Fuisz** in the device of **Weaver** to provide for a collection container to hold fluid. Applicants respectfully disagree.

Weaver is as discussed supra. **Fuisz** discloses fluid sampling devices to provide controlled sampling without discomfort to young subjects. The sampling device includes a sheet member surface expanse, a valve with a surface expanse and a collection unit (col. 1, ll 50-60). Sample is channeled from the sheet member expanse via the valve to the container. **Fuisz** further discloses that the container may include material such as cotton having sorption capacity in excess of the volumetric capacity of the container. **Fuisz** does not however teach or suggest using the sampling device with a tissue ablating system. Furthermore **Fuisz** teaches that the sampling device is used in conjunction with apparel such as diaper to which, such a sampling device can be affixed.

Weaver does not teach the abrasive member disclosed in the Applicants' device. The teaching of **Fuisz** does not remedy this deficiency. Thus the combination of **Weaver** and **Fuisz** does not render claim 1 obvious. Claim 32

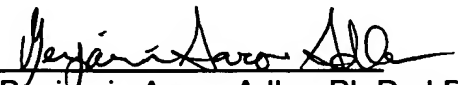


depends from claim 31, which depends from claim 1. Accordingly the combination of **Weaver** and **Fuisz** does not render claim 32 obvious. In view of the arguments presented above Applicants respectfully request that the rejection of claim 32 under 35 U.S.C. § 103(a) be withdrawn.

This is intended to be a complete response to the Office Action mailed October 4, 2005. Applicants submit that claims 1, 2, 4-6, 8, 13-26, 28, 29, 31-32, 34-37, 43, 44, 50, 51, 61 and 62 are in condition for allowance and respectfully request that claims 1, 2, 4-6, 8, 13-26, 28, 29, 31-32, 34-37, 43, 44, 50, 51, 61 and 62 be passed to issuance. If any issues remain outstanding, the Examiner is respectfully requested to telephone the undersigned attorney of record for immediate resolution. Pursuant to 37 C.F.R. §1.136(a), Applicants enclose a petition for extending the period of response to the Office Action mailed, October 04, 2005, in the above-referenced application, be extended for two (2) months to and including March 06, 2006. Please credit the \$225 extension fee under 37 C.F.R. §1.17(a) to the credit card identified on the enclosed Form PTO-2038. In the absence of Form PTO-2038, please debit any fees from Deposit Acct. No. 07-1185 upon which the undersigned attorney is allowed to draw.

Respectfully submitted,

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